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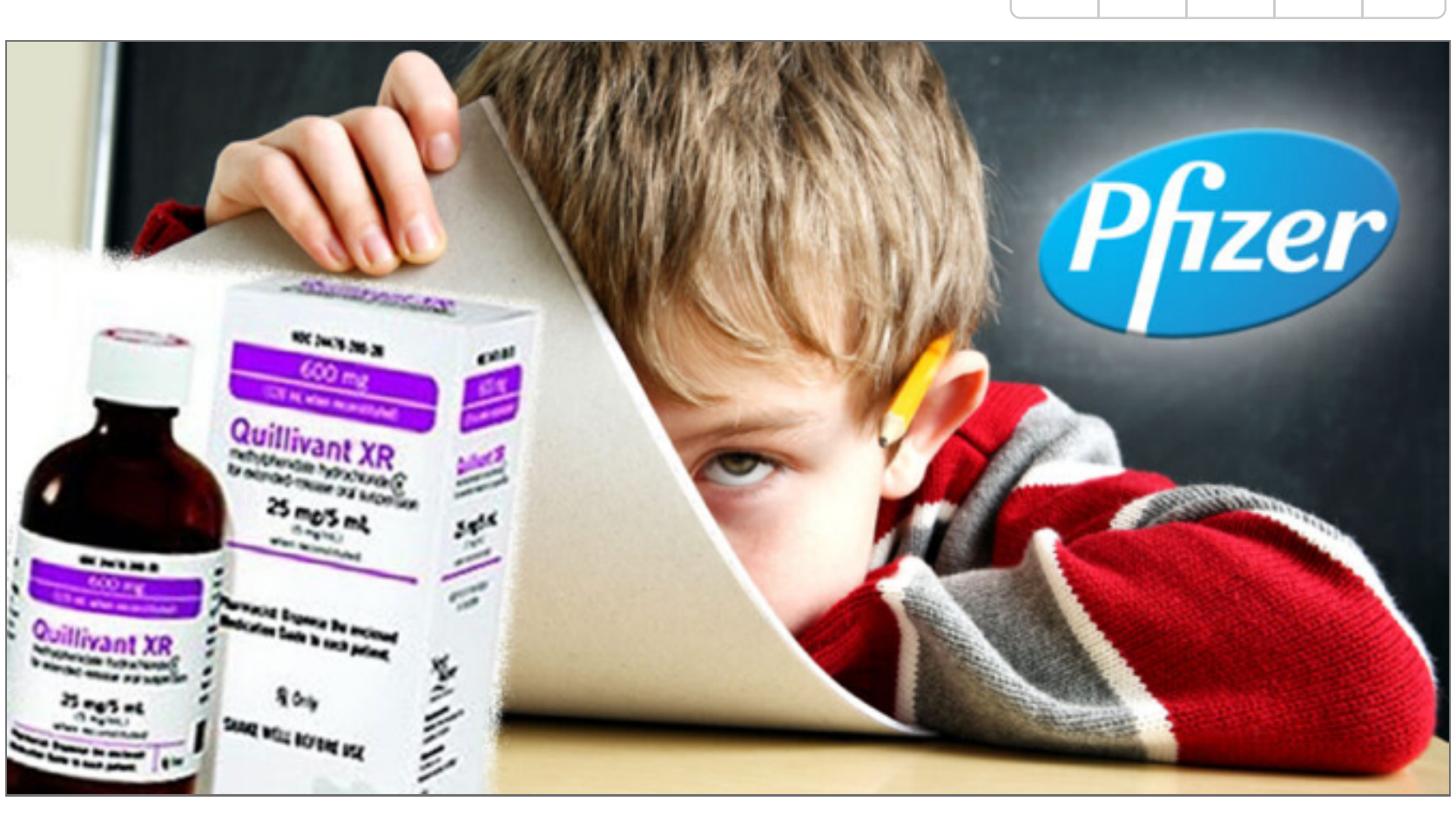
Texas Sues Pfizer for ‘Endangering Children’ by Selling Ineffective ADHD Drug

The suit alleges Pfizer knowingly distributed Quillivant XR, a drug used for treating attention-deficit/hyperactivity disorder, to children on Medicaid — despite the drug's pattern of failing quality control tests.

By **Suzanne Burdick, Ph.D.**

14



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Acting on behalf of the state of Texas, Attorney General Ken Paxton on Monday unsealed a lawsuit against Pfizer and its drug manufacturer, Tris Pharma, alleging the companies sold medication to children even though they knew the drug was ineffective and potentially unsafe.

The suit, filed in the Harrison County District Court, alleges Pfizer knowingly distributed a drug used for treating attention-deficit/hyperactivity disorder (ADHD) to children on Medicaid — despite the drug's pattern of failing quality control tests.

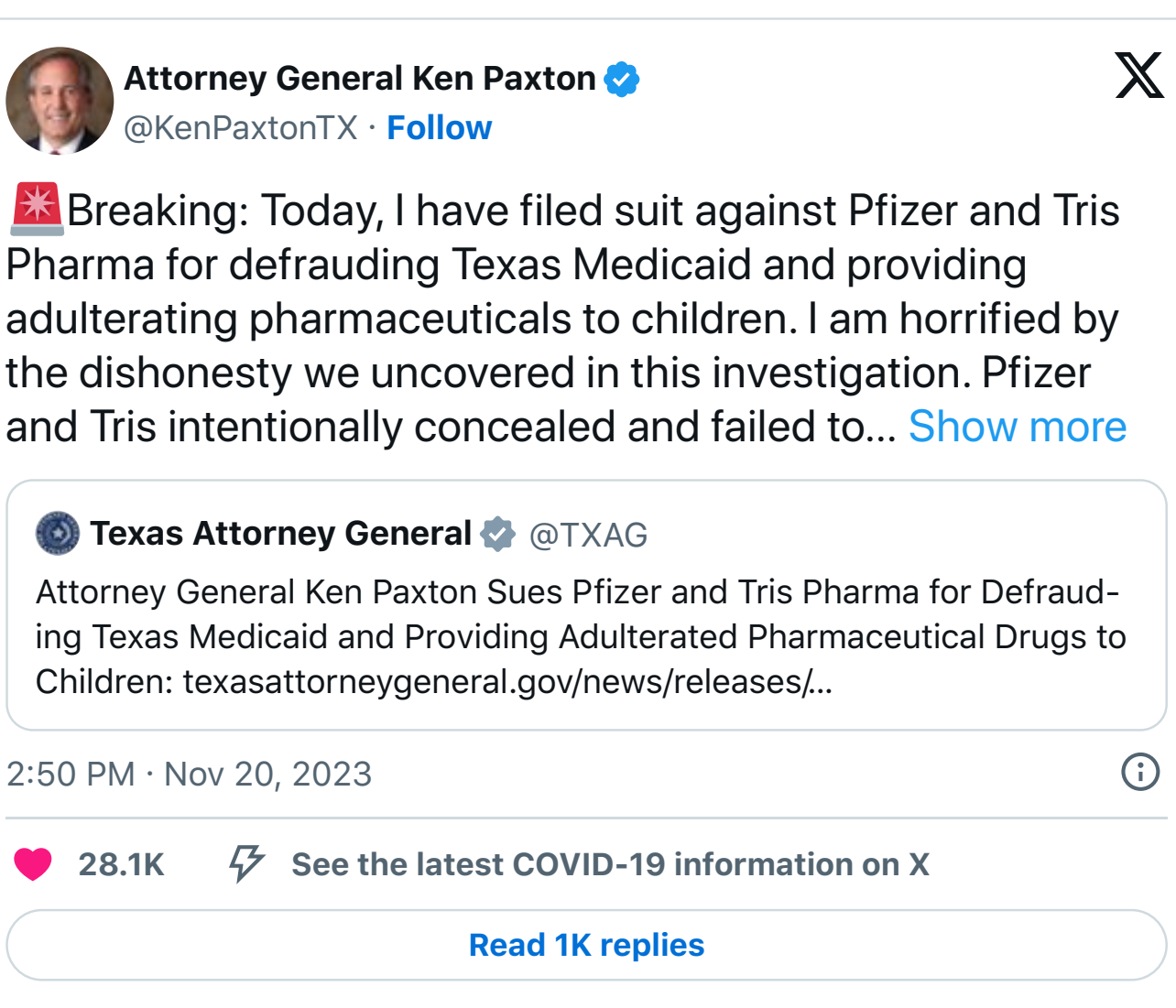
The drug, Quillivant XR, is a stimulant that affects brain and nerve chemicals involved in hyperactivity and impulse control.

From 2012-2018, “Pfizer and Tris continually manipulated Quillivant testing to hide poor manufacturing practices and defraud the Texas Medicaid program,” according to a press release.

During those years, many families complained that the medication failed to work. According to the complaint:

> “At no point did Defendants warn Texas Medicaid providers or decision-makers that Quillivant had known manufacturing issues affecting its efficacy, thereby depriving the Medicaid program of the crucial information it relies on. … As a result, thousands of Texas children received an adulterated Schedule II Controlled Dangerous Substance.”

In a tweet, Paxton said:



Attorney General Ken Paxton
@KenPaxtonTX · Follow

🚨Breaking: Today, I have filed suit against Pfizer and Tris Pharma for defrauding Texas Medicaid and providing adulterating pharmaceuticals to children. I am horrified by the dishonesty we uncovered in this investigation. Pfizer and Tris intentionally concealed and failed to… Show more

Texas Attorney General @TXAG
Attorney General Ken Paxton Sues Pfizer and Tris Pharma for Defrauding Texas Medicaid and Providing Adulterated Pharmaceutical Drugs to Children: texasattorneygeneral.gov/news/releases/…

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Commenting on the lawsuit, Kim Mack Rosenberg, acting general counsel for Children's Health Defense, said, “Pfizer once again is in the spotlight for alleged unethical and fraudulent activity.”

Rosenberg told The Defender:

> “I applaud the Texas AG for taking action here to protect some of Texas's most vulnerable children, those who rely on Medicaid for healthcare. To knowingly supply adulterated medication to vulnerable children is inexplicable and unconscionable.”

“Unfortunately,” Rosenberg added, “this is not the first time questions have been raised about Pfizer's conduct, including wrongdoing allegedly resulting in children dying in clinical trials in Nigeria in the 1990s and serious questions about Pfizer's COVID-19 injections and its treatment medication Paxlovid.”

Defendants in the suit include Pfizer, Tris and Tris CEO Ketan Mehta.

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The lawsuit stemmed from a whistleblower complaint made by Tarik Ahmed, who served as Tris' technology chief from 2013-2017.

The lawyers are suing for more than $1 million, including civil penalty fees, and are asking the court to force Pfizer and Tris to pay back to the state of Texas all profits received from selling Quillivant in the Texas Medicaid program “as a result of Defendants' unlawful acts” and, additionally, to pay back double that amount.

Lawyers with Paxton's office requested a trial by jury.

In 2017, Quillivant grossed roughly $193.3 million in U.S. sales. The drug was developed by NextWave Pharmaceuticals, which Pfizer bought in 2012 for $680 million.

The lawyers charged the defendants with defrauding the Texas Medicaid program “by providing adulterated pharmaceutical drugs to Texas children in violation of the Texas Medicaid Fraud Prevention Act, now known as the Texas Health Care Program Fraud Prevention Act (‘THFPA').”

The press release said, “For years, Tris altered the drug's testing method in violation of federal and state laws to ensure Quillivant passed regulatory hurdles and could continue to be sold.”

According to Reuters, Pfizer said in a statement that it had examined the suit's allegations on “multiple occasions” and “did not find any impact on the safety of the product.”

Pfizer said the case has no merit and will move to dismiss it.

A Tris spokesperson told Reuters in an email, “We categorically deny and intend to rigorously defend these allegations in the court of law.”

Drug failed quality control tests for years

Almost immediately after getting U.S. Food and Drug Administration (FDA) approval, Quillivant began failing routine quality tests. According to the complaint:

> “Beginning at least as early as October 2012, Tris quality control personnel observed that sample of Quillivant tested under FDA-required dissolution specifications were not generating passing results.
>
> “Dissolution testing is an important quality control tool used to measure whether a drug was properly manufactured, by comparing a simulated release of the drug to a standard set upon the drug's initial approval.
>
> “This in turn helps to predict whether the drug (as manufactured) will be released as expected in a patient's body — which is critical for ensuring proper and consistent patient dosing.”

The Quillivant samples formed lumps during the reconstitution phase of the test.

Instead of investigating why there were lumps, Tris “retrained” its analysts to shake the water/drug mixture longer and to conduct the test only when “foaming is absent from the suspension,” the filing said.

Even with these changes, Quillivant continued to fail dissolution tests. Tris then stopped using that testing method and switched to a new method.

“Alarmingly,” the filing said, “the new test method was not representative of real-world usage by patients, and worse, went against the pharmacy reconstitution instructions contained in the FDA-approved label for Quillivant.”

When quality control issues continued to arise, the companies told the FDA a “misleading” and “convenient narrative to explain away the problem.”

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Pfizer wanted to ‘fully exploit the economic potential of Texas Medicaid'

Meanwhile, Pfizer was petitioning Texas Medicaid to get Quillivant added to the program's preferred drug list — but said nothing about the drug's ongoing and unresolved quality control issues.

The FDA on March 26, 2018, sent a warning letter to Pfizer, informing the company that Quillivant was “adulterated starting in 2012 and continuing into 2018.”

Yet “even after receiving this clear and unequivocal assessment, neither Tris nor Pfizer alerted Texas Medicaid decision-makers to the FDA's serious findings,” the filing said.

The suit alleges that the companies avoided telling Texas Medicaid about the issues because “Quillivant's status with Texas Medicaid became a selling point.” The filing said:

> “Tris and Pfizer both recognized that Texas Medicaid business would be crucial for Quillivant's success.
>
> “To fully exploit the economic potential of Texas Medicaid, Defendants needed Medicaid decision-makers to add Quillivant to the VDP [Vendor Drug Program] Formulary and the Preferred Drug List.
>
> “These steps would effectively allow Medicaid providers to prescribe Quillivant to their Medicaid patients and would streamline the prescribing process by eliminating the need for the treating doctor to go through the burdensome process of obtaining prior authorization.”

Pfizer projected that Quillivant sales in Texas would significantly increase if the drug were added to the Texas Medicaid Preferred Drug List, as Texas was a “populous state with a disproportionately high percentage of children covered by Medicaid,” according to the complaint.

The Civil Medicaid Fraud Division of Paxton's office undertook the investigation.

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kaoshispano
9 days ago
PHARmafia is a public enemy for the human kind, one of the arms of devil in this ending Civilization.... the END.
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holisticpoet
9 days ago
My daughter was on the psychotropic medication resperidal. It was working at helping to control her problem. When it came off patent they switched her to the generic form of resperidal called resperidone. This did not have the same effects and she soon ended up back in the mental health center. There they would put her on resperidal and within 24 hours she would be back to normal. This happened several times and I told the staff that she needed to be on resperidal because when she took resperiddone she wigged out. The third time they told me that all the active ingredients were the same, I responded with: "doesn't that tell you that she is not deriving the benefits from the active ingredients?" I was ignored.

Several months later I was taking a class from a Chinese Naturopath. He was bragging how he sold herbs to the pharmaceutical companies to add to their psychotropic medication because without them they would not pass the trials. The thing is herbs cannot be listed as an active ingredient as they cannot be patented. Thus the generic form resperidone does not contain the herbs that offer the desired effect because they are considered inactive ingredients. This crippled my daughter psychologically. I will never forgive them for their heinous crimes against humanity.
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TruthHunter
9 days ago
Good for Texas. There is mass formation of greedy, power-hungry wanna-be gods.
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Beatrice
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This is an example of how ' safety' testing results were completely ignored. Going to the doctor today is much more dangerous than 25 years ago and imagine how dangerous it will be once your physician becomes a total slave to AI. Like big insurance does today, AI will decide which drugs are the preferred choice based on the programmed algorithms.
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Stephen Simac
9 days ago
None of them work as advertised, but this exposes Pfizer again as eager to market completely fraudulent and harmful potions to the poorest people. Children on Texas Medicaid- not expanded with ObamaCare.
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> **Beatrice** ➦ Stephen Simac
> 9 days ago
> Medicaid and Obamacare are both lethal. The ACA was nothing more than a promotion to bolster profits for big insurance and big pharma
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Gary Brown
5 days ago
May 16, 2023 Texas AG Demands COVID-19 Vax Makers Produce Evidence on Safety & Efficacy

State Attorney Generals have led the way on many COVID-19-related freedom issues, including a response to President Joe Biden's COVID-19 vaccine mandate for companies with 100 or more employees. A group of state AGs challenged and took the mandate to the Supreme Court. The High Court's decision that the OSHA large-employer vaccine mandate was unlawful was the work of these AGs, as well as other parties opposing COVID-19 vaccine mandates. As noted by Tennessee's AG, many states came forward to challenge the OSHA mandate.

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mcwinaz
7 days ago
Yet another lawsuit against these twits... Can't keep up w/them Pfizer??? Good. Hoping all of these solidify your doom, similar to what is happening to J&J and their "non-asbestos" talc powder..
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Jane Hersey
7 days ago
The nonprofit Feingold Association (www.feingold.org) has been helping children with various behavior and learning problems since 1976. For all these years, our volunteers -- both parents and professionals -- have helped families identify the most likely reasons for the unwanted symptoms. The Feingold Diet is a simple, risk-free way to determine why a child (or adult) is experiencing problems, and we have not found that a deficiency in drugs is the reason!
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PonyBoy
8 days ago
Big Pharma and the uniparty have colluded to kill and maim millions all the while banking Billion$.
They all deserve a speedy trial, and unforgiving punishment.
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Ricky Ricardo
8 days ago
If the truth were "allowed", the truth would be that Pfizer and all the other Big Pharma minions are a threat to all of humanity - by their very existence!
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craig martin
8 days ago
What a awesome time it is becoming, people waking up to the TRUTH ,very few were at this point just a few years ago ,this is like i say Awesome great minds communicating roughly on the same page . Now im going to expose the biggest lie they have created are ya ready , Back when we were all brought in to this life they [Elite] created a CORPORATE fictional caractor from our Birth with out our Consent yes that's right say hello to your STRAW MAN /WOMAN all STATUTS & ACTS only apply to CORPORATIONS [FACT] all CAPs which is DOG LATTIN the only thing that can be in all CAPs is a CORPORATION , don't believe me dig out your Birth Certificate , Drivers License notice its in all CAPs that is the CORPORATE you not the live man/woman we all have 2 birth certificates living and DEAD as well ever notice in Grave yards all the TUMBE STONES are in all CAPs yep were all lost at sea DEAD ,learn how to separate your self from the CORPORATE you and ACTs & STATUTS will not apply to you , Hummmm what belongs to Ceasor give back to Ceasor . as well this is where it gets interesting your ALL CAPs you is worth millions and you as the Beneficiary of that account can actually pay off hydro bills phone bills , mortgages etc. but you need to study and learn this very well eg, dot your i s & cross your T s sort of speak cest cu via trust of 1666 , isent that # interesting so much more to this i don't have the patentse to keep typing with one finger not very key board savvy but this is enough info to get one started if you are interested and how can you not be ps. MANDATES & ORDERS are not Law [fact] YAHUAH Bless.
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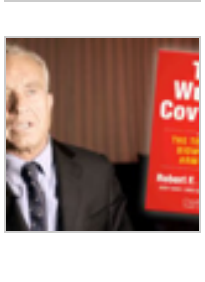

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